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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/719,316	12/11/2000	Yasuhiko Shimizu	55475(968)	7005

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EXAMINER	
BOYD, JENNIFER A	

ART UNIT	PAPER NUMBER
1771	

DATE MAILED: 03/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/719,316	SHIMIZU, YASUHIKO	
	Examiner	Art Unit	
	Jennifer A Boyd	1771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 December 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5 and 8-28* is/are pending in the application.

4a) Of the above claim(s) *11-28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3, 5 and 8 - 10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 9, 2004 has been entered. The Applicant's Amendments and Accompanying Remarks, filed December 9, 2004, have been entered and have been carefully considered. Claims 1, 3, 5, 8 and 10 are amended, claim 7 is cancelled, claims 11 – 28 are withdrawn and claims 1 – 3, 5 and 8 - 10 are pending. In view of Applicant's amendments to claims 1, 5 and 8, the Examiner withdraws the 35 USC 112, 2nd paragraph rejection as detailed in paragraphs 3 – 4 of the Office Action dated June 17, 2004. In view of Applicant's cancellation of claim 7, the rejection of claim 7 is withdrawn as set forth in the Office Action dated June 17, 2004. Despite these advances, the invention as currently claimed is not found to be patentable for reasons herein below.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

3. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the

invention. Claims 2 – 3 and 9 - 10 are rejected as being dependent on rejected independent claim 1.

4. Claim 1 recites on line 1 that the collagen material is "consisting of", which is considered to be closed language which excludes any element, step, or ingredient not specified in the claim. However, on lines 14, 16, 18 and 20 of claim 1, the Applicant uses the language "composed of". For consistency, please amend the claim to recite "consisting of" in all instances.

Claim Rejections - 35 USC § 102/103

5. Claim 5 is rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bell (US 6,179,872).

Bell is directed to a biopolymer matt for use in tissue repair and reconstruction (Title).

As to claim 5, Bell teaches a nonwoven made of biopolymers such as collagen (column 12, lines 15 – 20). Bell teaches that objects can be embedded in the nonwoven material to alter its tear properties such as fragments of resorbable polymers (column 10, lines 15 – 30). Bell teaches that resorbable polymers include poly-1-lactic acid (polylactic acid) and poly-1-glycolic acid (polyglycolic acid) (column 12, lines 27 – 33). Bell teaches that the matt of collagen material or composite matt may be washed by various mild methods such as 0.001 – 0.1 M hydrochloric acid (column 16, lines 15 – 23). Bell teaches that the washing step occurs after freeze drying and can be freeze dried again after the washing step (column 16, 25 – 30).

Although Bell does not explicitly teach the claimed collagen material having one-point support tensile force of at least 5 N and rupture resistance tensile force of at least 15 N in the wet

state (for a thickness of 1 mm), it is reasonable to presume that collagen material having one-point support tensile force of at least 5 N and rupture resistance tensile force of at least 15 N in the wet state (for a thickness of 1 mm) is inherent to Bell. Support for said presumption is found in the use of like materials (i.e. a collagen material comprising a non-woven fabric-like matrix composed of collagen and embedded with resorbable polymers such as polylactic acid or polyglycolic acid) which would result in the claimed property. The burden is upon the Applicant to prove otherwise. *In re Fitzgerald* 205 USPQ 594. In addition, the presently claimed property of collagen material having one-point support tensile force of at least 5 N and rupture resistance tensile force of at least 15 N in the wet state (for a thickness of 1 mm) would obviously have been present once the Bell product is provided. Note *In re Best*, 195 USPQ at 433, footnote 4 (CCPA 1977).

Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same or an obvious variant from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process. *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985). The burden has been shifted to the Applicant to show unobvious differences between the claimed product and the prior art product. *In re Marosi*, 218 USPQ 289, 292 (Fed. Cir. 1983).

Claim Rejections - 35 USC § 103

6. Claims 8 and 10 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Bell (US 6,179,872) in view of Yasuhiko (WO 98/22157). The details of the rejection can be found in paragraph 7 of the previous Office Action dated October 15, 2003. The rejection is maintained.

Allowable Subject Matter

7. Claim 1 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action. Claims 2 – 3 and 9 are rejected as being dependent on rejected claim 1 but likewise would be allowable if amended to overcome the 35 U.S.C. 112, 2nd paragraph rejection. The reasons for allowance have been set forth in paragraph 8 of the Office Action dated October 15, 2003.

Response to Arguments

8. Applicant's arguments filed December 9, 2004 have been fully considered but they are not persuasive.

9. In response to Applicant's Arguments that the features recited in claim 5 are neither disclosed nor suggested by the Bell patent, the Examiner respectfully argues the contrary. The Applicant argues that the instant invention is frozen and sublimed by performing a freezing and freeze-drying procedure so consequently no salts are crystallized in the collagen material. The Applicant further argues that Bell specifically calls for using a sodium, ammonium or potassium hydroxide solution (known in the art to be salt solutions) in connection with fibril formation. The Applicant submits that the presence of salt in the resultant collagen material as required by Bell would result in an unstable and relatively weak structure. The Applicant also submits that the

instant invention has no salts and therefore the lack of presence of salt would result in a morphogically stable and strong structure. The Examiner submits that the Applicant has not provided evidence to support Applicant's arguments. The Examiner requests that the Applicant submit a 37 CFR 1.132 Declaration to establish that the presence of salt would result in an unstable and weak structure. It is highly suggested to demonstrate that the invention of Bell would not have a one-point support tensile force of at least 10 N and a rupture resistance tensile force of at least 25 N in the dry state and has one-point support tensile force of at least 5 N and rupture resistance tensile force of at least 15 N in the wet state (for a thickness of 1 mm) as required in Applicant's claim 10 in order to provide evidence that is commensurate in scope with the claims. Alternatively, the Applicant may wish to amend the claims to use "consisting of" language. It should be noted that the transitional phrase "consisting of" excludes any element, step, or ingredient not specified in the claim (i.e. use of a salt solution for fibril formation). *In re Gray*, 53 F.2d 520, 11 USPQ 255 (CCPA 1931); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948)

10. In response to Applicant's Arguments that the Bell patent describes the use of a chemical crosslinking treatment whereas thermal dehydration crosslinking is utilized in accordance with the present invention, it is noted that the features upon which applicant relies are not recited in the rejected claims. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). If the Applicant requires that the collagen material is subjected to a thermal dehydration crosslinking process, the Applicant should put such a limitation into the claims.

11. In response to Applicant's Arguments that Yasuhiko in combination with Bell does not teach Applicant's invention, the Examiner respectfully argues the contrary. It should be noted that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The Examiner uses the Bell reference to set forth the embedding of a resorbable polymer into a collagen non-woven matt. The Examiner has incorporated Yasuhiko to set forth the exact structure of the collagen fibers within the matt and the tensile strength of the matt. In combination, the Examiner suggests that Yasuhiko can be used to modify the non-woven structure of the resorbable polymer embedded non-woven of Bell to create a material with good medical characteristics and the capability of suturing as suggested by Yasuhiko on page 5, paragraph 1.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer A Boyd whose telephone number is 571-272-1473. The examiner can normally be reached on Monday thru Friday (8:30am - 6:00pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrel Morris can be reached on 571-272-1478. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jennifer Boyd
February 25, 2005

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